Department of Health and Human Services
National Institute of Environmental Health Sciences
National Cancer Institute

Minutes of the Research Process Subcommittee of the Interagency Breast Cancer and Environmental Research Coordinating Committee

March 3, 2011

The Research Process Subcommittee of the Interagency Breast Cancer and Environmental Research Coordinating Committee was convened for a meeting on March 3, 2011 at 1:00 p.m. via conference call. The Chair of the subcommittee is Michael Gould, PhD of the University of Wisconsin.

Subcommittee Members Present
Michael Gould, PhD
Laura Nikolaides, MS
Kenneth Portier, PhD
Dale Sandler, PhD
Gayle Vaday, PhD

NIH Staff Present
Jennifer Collins, MR
Nonye Harvey, MPH
Heather Shaw, MD, MPH

Other
Michele Forman, PhD, MS

I. BACKGROUND

The Interagency Breast Cancer and Environmental Research Coordinating Committee (IBCERCC) is a congressionally mandated body established by the National Institute of Environmental Health Sciences (NIEHS), in collaboration with the National Cancer Institute (NCI). This Committee is comprised of 19 voting members, including representatives of Federal agencies; non-federal scientists, physicians, and other health professionals from clinical, basic, and public health sciences; and advocates for individuals with breast cancer.

The Committee's primary mission is to facilitate the efficient and effective exchange of information on breast cancer research activities among the member agencies, and to advise the NIH and other Federal agencies in the solicitation of proposals for collaborative, multidisciplinary research, including proposals

to further evaluate environmental and genomic factors that may be related to the etiology of breast cancer. The Committee serves as a forum and assists in increasing public understanding of the member agencies' activities, programs, policies, and research, and in bringing important matters of interest forward for discussion.

The objectives of the Research Process (RP) Subcommittee of the IBCERCC are integrated and dependent on the objectives and activities of the other Subcommittees[1] of the IBCERCC and include the following: to set research priorities (based on work of the State-of-the-Science Subcommittee), to decrease redundancies across federal and non-governmental organizations, to develop a process for soliciting research, to foster collaborations (based on the work of the Research Translation, Dissemination, and Policy Implications Subcommittee), to highlight peer review issues, and to identify most appropriate models for agencies to work together.

The IBCERCC RP Subcommittee held its second meeting, hosted by NIEHS and the NCI, via conference call on March 3, 2011 beginning at 1PM EST. Attendees of the meeting included Subcommittee members, NIH staff, and the IBCERCC Chair. The meeting agenda included a discussion on the individual written documents generated as action items from the last meeting, barriers to research, and how to facilitate innovative thinking about research and research process. In addition, the Subcommittee discussed the chapters for the Subcommittee's portion of the IBCERCC Report.

II. Discussion

Michael welcomed everyone to the call and began the discussion regarding the individual written documents and slides that were requested from the group as an action item from the February 23, 2011 meeting of the RP Subcommittee.

Ken described the some of the NCI research portfolio data that is publically available. The table he presented included three areas of particular interest to the RP Subcommittee: 1) research topics (SICs) w/ percent relevance, 2) cancer types (disease sites) w/ percent relevance, and 3) common scientific outline. He noted that research grants have measures of relevance to key topics and presented a listing, pointing out that there were few environmental topics besides smoking and pesticides. There are limitations with regard to the number of boxes that can be checked (a primary and a secondary code). The selections are really an indication of how the researcher views the emphasis of their research. Nonye informed the group that NCI staff have internal tools that allow them to go into more depth. She will provide a summary of the NCI internal coding.

Michael requested that the NIH staff look into how OD conducts their portfolio analyses. Michelle also requested NIH staff look into the term matrix that the Center for Cancer Research has been developing. Gayle suggested NIH staff contact Carole Christian, who used to be a DOD but is currently at NCI doing

[1] The other Subcommittees of the IBCERCC are the State-of-the-Science Subcommittee (Chair, Michele Forman) and the Research Translation, Dissemination, and Policy Implications Subcommittee (Chair, Jeanne Rizzo).

portfolio analysis. Ken mentioned that he would look at the Health Research Alliance that has a common database used by several funders, to see what breakdowns they use.

Ken, Gayle, Nonye, and Jenny will work together to determine the active portfolio of grants in the Federal sector in the area of breast cancer and environmental research. They will identify keywords and break the data down into categories.

Next, Laura described the consumer advocate involvement in allocating scientific resources. She explained that patient advocate groups are attempting to find new ways of allocating scientific resources to ensure progress is made in reducing the morbidity and mortality of disease. In large part, just having consumer advocate involvement in the decision making ensures that research is focused on the end result and that resources are allocated to the research that will be the most impactful. An example of this approach is being piloted by the National Breast Cancer Coalition to accelerate progress toward eradicating the disease. Diverse groups of scientists from industry, academia, and government, are working together with advocates to identify key research questions, and then are developing strategic plans for answering those questions. In a pilot program, seed grants are being awarded to working teams of advocates and scientists to develop a preventive vaccine for breast cancer within five years. Grant money is awarded during annual meetings after real time development of collaborative work proposals. The process is advocate driven and focused on the end result. NBCC plans to use this model in further research collaborations directed at the prevention of breast cancer, and the prevention of metastatic disease. Michael asked Laura what process what used to decide on these two areas. Laura explained that NBCC felt that these were the most important ways to eradicate disease (resources were already focused on treatment of disease).

Gayle discussed some of the approaches of the DOD with regard to fostering innovation. When the DOD BCRP was initiated in 1993, the Army solicited the IOM to provide recommendations on how to administer the program. An important recommendation made by the IOM committee was to establish programmatic goals that channel research funds in directions that "stimulate innovative ideas, involve interdisciplinary research…" As a result, over the years, the DOD BCRP has developed and utilized several award mechanisms to foster innovation and promote multidisciplinary research and collaborations. These award mechanisms have ranged in size from $75K to several million dollars per award. Examples are briefly described in the table below:

Award Mechanism	Description
Idea Award	Promotes innovative, high-risk/high-reward research ideas that are still in the early stages of development and have the potential to yield highly impactful data and new avenues of investigation. $375K for 2-3 years.
Synergistic Idea Award	Supports collaborations between two independent investigators who address an innovative, high-risk, potentially high-reward

	research question from synergistic and complementary perspectives. $500K for 2 years.
Multidisciplinary Postdoctoral Award	Supports exceptionally talented postdoctoral fellows in obtaining significant training and experience in at least two discrete disciplines so that they may more effectively pursue an independent career at the forefront of breast cancer research. $450K for 3 years.
Era of Hope Scholar Award	Supports exceptionally talented individuals who are early in their careers and have high potential for innovation in breast cancer research. $2.5M for 5 years.
Innovator Award	Supports visionary individuals who have demonstrated creativity, innovative work, and leadership in any field, and have high potential for ground-breaking achievements in breast cancer. $5M for 5 years.
Multi-Team Award (formerly Center of Excellence Award)	Supports the creation of a collaborative research project among three investigators and their research teams; creates an environment that fosters and supports innovation and creativity, with consistent interaction across team members; expected to transform the research process through the integration of basic and clinical disciplines, substantive cross-disciplinary training, and integral participation of consumer advocates; requires one basic scientist, one clinician, and one additional individual from any area of expertise (e.g. epidemiology). Ranges from $4.5M to $20M for 5 years.

Gayle mentioned that even though innovation is included in all the awards and the reviewers are asked to fund not just good science, but innovative research, not all the applications received are innovative. In order to make an impact, we need to be able to tell the applicants what we want. Not all grants in the DOD BCRP address environment and breast cancer. One of the challenges we face is how to solicit people to come up with innovative ideas in environmental health research. There was discussion about how the RFA mechanism could help with this challenge.

Cheryl was not on the call but Michael summarized her assignment and thoughts on investigator initiated ideas versus targeted strategies. While collaborations are good for innovation, key innovative ideas come from individual level research. There was discussion about how to balance getting new / junior investigators interested and focused on environmental health while integrating different disciplines in the breast cancer and environment research field.

Dale described the different ways to stimulate research ideas that will be potentially one shot deals. She gave an example of the Sister Study being a huge resource to researchers to study environmental contributors to quality of life / survivorship. There was a day and a half meeting where speakers of different disciplines were invited to talk on state of the art and survivorship research and how to get resources to do what was innovative. The cost of the workshop was minimal, limited to speaker travel with no honoraria. There is also the opportunity to submit conference grants to the NIH to fund such workshops.

Michael led the discussion on identifying barriers and solutions to research. From the advocate's perspective, Laura identified one barrier to be incentives, i.e. what's driving the research and how much is allocated to it. Another barrier mentioned is that there are few people going into the field of environment and cancer / disease research but it's not clear why. Another barrier discussed is visibility and the educational process; editors of top journals are not knowledgeable of the field so a recommendation would be to sponsor a workshop for editors of top journals. In addition, sponsoring a workshop for young investigators to educate them in these areas could help deal with the barrier. Laura agreed that in addition to recruiting young investigators in the field, we should focus on integrating a variety of disciplines on specific areas.

Michael discussed expectations and plans for generating an outline of 'process' chapters for the report. The first chapter will focus on summary of federally funded grants and portfolio analysis. The second chapter will focus on summary of funding models of breast cancer and environment research and how to evaluate them. The third chapter will focus on defining what innovation is and what we mean by high risk / high return.

Action Items due March 25th

- Identify barriers to research - each member is to write up 2 - 3 barriers to research as well as solutions **(ALL)**
- Provide ideas of being good stewards of our resources; balance between investigator initiated ideas vs. targeted strategies **(Cheryl)**
- Provide ideas on models being used in health research; Federal agencies should take more systems approach - RFAs writers should include social scientists, etc. to get broader perspectives **(Sally)**
- Provide a summary of the NCI internal coding **(Nonye)**
- Provide summary of draft federal portfolio analysis **(Nonye, Jenny, Ken, Gayle)**
- Provide summary of state funding models – California, Texas **(Sally, Cheryl)**
- Provide summary of funding models from a private sector perspective e.g. Komen **(Laura)**
- Provide summary of funding model – EPA **(Sally)**
- Provide summary of funding model – NIH Intramural and Extramural **(Dale)**
- Define innovation and what it means to be high risk **(Michael, Cheryl, Gayle)**

III. Adjournment

The meeting adjourned at 3:15 p.m. on March 3, 2011.

CERTIFICATION

I hereby certify that, to the best of my knowledge, the foregoing minutes and attachments are accurate and complete.

/Michael Gould/
Michael Gould, PhD
Chairperson
Research Process Subcommittee
Interagency Breast Cancer & Environmental Research Coordinating Committee

/Gwen W. Collman/
Gwen W. Collman, PhD
Executive Secretary
Research Process Subcommittee
Interagency Breast Cancer & Environmental Research Coordinating Committee

Proper signatures
Treat as signed, § 1.4(d)(2)